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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,394	12/10/2001	Yi Li	PF187D1C1	8404

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EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,394	LI ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *NA*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 drawn to a polynucleotide encoding a polypeptide of SEQ ID No.2, vectors, host cells and methods of expressing a polypeptide, classified in class 536, subclass 23.5.

II. Claims 7 and 8, drawn to a polypeptide of SEQ ID No.2 , classified in class 530, subclass 350.

III. Claim 9, drawn to an antibody, classified in class 530, subclass 388.22.

IV. Claim 10, drawn to an agonist of a polypeptide, classification to dependent on the structure of the compound.

V. Claim 11, drawn to an antagonist of a polypeptide, classification to dependent on the structure of the compound.

VI. Claim 12, drawn to a method of treatment comprising administering an agonist of a polypeptide, classification to dependent on the structure of the compound.

VII. Claim 13, drawn to a method of treatment comprising administering an antagonist of a polypeptide, classification to dependent on the structure of the compound.

VIII. Claim 14, drawn to a method of gene therapy comprising administering a DNA encoding an agonist of a polypeptide, classified in class 514, subclass 44.

IX. Claim 15, drawn to a method of gene therapy comprising administering a DNA encoding an antagonist of a polypeptide, classified in class 514, subclass 44.

X. Claim 16, drawn to a method for identifying agonists of a polypeptide, classified in class 436, subclass 501.

XI. Claim 17, drawn to a method for identifying antagonists of a polypeptide, classified in class 436, subclass 501.

XII. Claim 18, drawn to a method for identifying binding partners of a polypeptide, classified in class 436, subclass 501.

XIII. Claim 19, drawn to a method of diagnosis comprising the determination of a nucleic acid sequence, classified in class 435, subclass 6.

XIV. Claim 20, drawn to a method of diagnosis comprising the detection of a polypeptide, classified in class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-V are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make

the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Additionally, although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

The agonist of Group IV and the antagonist of Group V are patentably distinct, one for the other, because they are functional opposites and one is not required for the use of the other. Additionally, the agonist of Group IV and the antagonist of Group V are patentably distinct from the products of either of Groups I, II, and III because, in each case, each of the products can be used in materially and functionally different ways and one is not required for the use of the other.

The agonist of Group IV and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the agonist of Group IV and the can be used in a materially different way, with different goals, than in that required of the method of Group VI, e.g. the agonist could be used to label the polypeptide of Group II to determine the tissue specific expression of the polypeptide . This example is equally true of the relationship between the antagonist of Group V and the method Group VII. Furthermore, the nucleic acid of Group I is patentably distinct from the method of Group XIII because the nucleic acid can be used in a materially different way than that required of Group XIII such as to produce the polypeptide of Group II.

The nucleic acid of Group I is patentably distinct from each of the methods of Groups X-XII, because, although the nucleic acid of Group I could be used to produce the polypeptide required of a ligand binding assay used in the methods of Groups X-XIII, the polypeptide could alternatively be obtained in a completely different manner such as affinity chromatography from natural sources followed by reconstitution in lipid vesicles. Similarly, the polypeptide of Group II is patentably distinct from each of the methods of Groups X-XII, because, although the methods of Groups X-XII can be practiced using the purified polypeptide of Group II, these methods can also be practiced by expressing the nucleic acids of Group I in a host cell and then using the host cell in the ligand binding assays.

The agonist of Group IV and the methods of Groups X and XII are patentably distinct because the agonist of Group IV can be used in materially different ways, with different goals, then those required of the methods of Groups X and XII, such as in the method of treatment of Group VI. Similarly, the antagonist of Group V and the methods of Groups XI and XII are patentably distinct because the agonist of Group V can be used in materially different ways, with different goals, then those required of the methods of Groups XI and XII, such as in the method of treatment of Group VII.

The nucleic acid of Group I is patentably distinct from each of the methods of Groups VI-IX, and XIV because the use of one is not required for the use of the other. Similarly, the protein Group II is patentably distinct from each of the methods of Groups VI-IX, XIII and XIV because the use of one is not required for the use of the other. Additionally, the antibody of Group III is patentably distinct from each of the methods of Groups VI-XIII because the use of one is not required for the use of the other. Further, the agonist of Group IV is patentably

distinct from each of the methods of Groups VII-IX, XIII and XIV because the use of one is not required for the use of the other. Additionally, the antagonist of Group V is patentably distinct from each of the methods of Groups VI, III-IX, XIII and XIV because the use of one is not required for the use of the other. Furthermore, the antibody of Group III is patentably distinct from the method of Group XIV, because, although the antibody can be used in the method of Group XIV, detection of a polypeptide can also be accomplished using the labeled agonist of Group IV or the antagonist of Group V.

Additionally the agonist of Group IV and the method of Group XI are patentably distinct because one is not required for the use of the other. Similarly, the antagonist of Group V and the method of Group X are patentably distinct because one is not required for the use of the other

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups VI - XIV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group VI requires administering an agonist, which is not required by any of the other groups. Group VII requires administering an antagonist, which is not required by any of the other groups. Group VIII requires administering a DNA encoding an agonist, which is not required by any of the other groups. Group IX requires administering a DNA encoding an antagonist, which is not required by any of the other groups. Group X requires that an agonist be identified, which is not required by any of the other groups.

Group XI requires that an antagonist be identified, which is not required by any of the other groups. Group XII requires that a binding partner of a polypeptide be identified (i.e. this includes binding partners which are neither agonists nor antagonists of the polypeptide), which is not required by any of the other groups. Group XIII requires determining a nucleic acid sequence, which is not required by any of the other groups. Group XIV requires the detection of a polypeptide, which is not required by any of the other groups.

Therefore, a search and examination of all nine methods in one patent application would result in an undue burden, since the searches for the nine methods are not co-extensive, the classification is different, and the subject matter is divergent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-

0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER

June 10, 2004